

in Appendix A reflects FDA's thinking at the time of publication. It was envisioned at the time of publication of GFI #152 that the Agency would reassess the rankings provided in Appendix A periodically to confirm that the rankings are consistent with contemporary practices and needs. As noted in GFI #152, the development of new antimicrobial drugs for human therapy, the emergence or re-emergence of diseases in humans, and changes in prescribing practices, are some factors that may cause the human medical importance rankings to change over time.

Given the considerable advances in science that have taken place since 2003, new relevant information has become available. In light of those advances and the new information now available, FDA published a document in the **Federal Register** of October 13, 2020 (85 FR 64481), announcing a public meeting and requesting comments on a concept paper entitled "Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs." FDA received more than 60 comment submissions from pharmaceutical companies, academia, organizations, and private citizens on this concept paper. In the **Federal Register** of December 19, 2022 (87 FR 77619), FDA announced the availability of draft revised GFI #152 entitled "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern." Interested parties were originally given until March 20, 2023, to comment on the guidance. In the **Federal Register** of March 7, 2023 (88 FR 14170), FDA extended the comment period for the guidance to May 19, 2023.

FDA received over 9,200 comments on the draft guidance that appear to have been the result of 2 write-in campaigns. These campaigns asked FDA to "quit delaying efforts to stop the overuse of antibiotics in meat production," "stop allowing the meat industry to use antibiotics to counter unhealthy conditions in livestock facilities," "treat all drugs used in human medicine as medically important. . .," and said that "FDA must make a plan for updating [the list of medically important drugs in Appendix A] more frequently." With the exception of the comment that FDA should treat all drugs used in human medicine as medically important, these comments expressed broad policy views and did not address specific recommendations in the draft guidance.

Twenty-two comments outside of the write-in campaigns were submitted by animal pharmaceutical companies, food animal producers, veterinarians, consumer and public health interest groups, a State agriculture department, and other organizations and individuals. These comments offered feedback and suggestions addressing specific recommendations in the draft guidance.

FDA considered all comments as we finalized the guidance. In the final guidance, we made several changes, including: providing a more detailed description of hazard characterization; combining sections of the guidance discussing Application of Risk Management Strategies and Risk Management; clarifying why the ranking of medically important drugs in Appendix A should not be used alone to dictate risk management decisions, but instead be used to inform one component of the risk assessment process as described in the guidance; and addressing why FDA excludes topicals in our ranking of medically important antimicrobials. In addition, we made editorial changes to improve clarity.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M-25-20, and finds this action to be neither regulatory nor deregulatory under this E.O.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910-0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance->

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Organ Procurement and Transplantation Network Board of Directors and Committee Member Applications and Forms

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 5, 2026.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Organ Procurement and Transplantation Network Board of Directors and Committee Member Applications and Forms, OMB No. 0906-New.

Abstract: The Organ Procurement and Transplantation Network (OPTN) is a

public-private partnership that links professionals involved in the donation, procurement, and transplantation system in the United States. The OPTN focuses on promoting long, healthy, and productive lives for people with organ failure. The OPTN also aims to increase opportunities for transplants, optimize organ use, enhance efficiency, and prioritize patient care. The OPTN Board of Directors (BOD) is authorized by the National Organ Transplant Act of 1984 (*see* 42 U.S.C. 27(b)(1)(B)), and the operation composition of the OPTN BOD are further codified in federal regulation under the regulations implementing the National Organ Transplant Act (*see* 42 CFR 121.3(a)). These regulations also provide that the OPTN BOD shall establish committees as are necessary to perform the duties of the OPTN and describe the composition of these committees (*see* 42 CFR 121.3(a)(4)).

As part of the ongoing OPTN Modernization Initiative (<https://www.hrsa.gov/optn-modernization/learn-more-about-modernization>), HRSA seeks OMB approval of applications to be completed by candidates interested in volunteering to serve on the OPTN BOD and/or on the committees that support the BOD. Members of the OPTN BOD and committees do not receive payment for this work. HRSA also seeks approval of conflict of interest (COI), code of conduct, confidentiality, and attestation forms to be completed by the selected/confirmed members of the OPTN BOD and committees on an annual, tri-annual, or ad hoc basis. The OPTN BOD consists of 35 members who serve 2- to 3-year terms and are supported by 21 committees with a total of approximately 419 members with the same term limits. Select members of the BOD also serve on committee(s) as Visiting Board Members. In addition, there are ad hoc committees or BOD workgroups that may be established to work on time-limited issues, and 20 of these members would fill out the annual COI form as well, as other members already receive the form as per their other OPTN committee roles. Given some committee turnover, there are approximately 505 committee and BOD members filling out the annual COI form and attestation form every year.

Need and Proposed Use of the Information: HRSA and the OPTN

anticipate collecting committee and BOD applications on an annual basis for committee and board openings. Resumes are requested and required for Board applicants and requested but not required for committee applicants. To ensure applicants to the OPTN BOD and committees have the appropriate expertise, the proposed applications will collect information including candidates' professional background, expertise, experience in organ donation and transplantation and areas of interest. The OPTN and its Nominating Committee, with HRSA oversight, will evaluate the applications to analyze qualifications and support a structured nomination and selection process. The application information will help ensure the OPTN governance bodies are composed of individuals with the necessary knowledge, skills, and perspectives to effectively oversee and support the nation's organ donation and transplantation system.

In addition, annual COI disclosures will be collected from BOD and committee members upon their election/selection or annual anniversary. The BOD and Membership and Professional Standards Committee members will also submit COI updates on a triannual basis as well as fill out an ad hoc COI form when needed. HRSA and the OPTN will use information collected via the selected BOD and committee members' COI forms to routinely identify, monitor, prevent, and address actual, potential, or appearances of COI relating to the operation of the OPTN. HRSA will use this information to strengthen oversight and accountability within the OPTN to enhance trust and confidence among stakeholders and the public. Without access to this information, HRSA and the OPTN would be less able to prevent potential conflicts of interest, which could jeopardize the independence and objectivity of the OPTN BOD and committees that inform national organ procurement and transplantation policy.

Upon committee election or appointment and volunteer orientation, BOD and committee members will complete and submit an Attestation Form, Confidentiality Agreement, as well as the Code of Conduct. The Code of Conduct, Confidentiality Agreement, and Attestation are collected to ensure that OPTN BOD and committee members annually acknowledge their

obligations to act in the best interests of the OPTN, comply with applicable ethical and conduct requirements, protect confidential information, and uphold the standards necessary to maintain good standing and public trust in OPTN governance.

Likely Respondents: Respondents completing the application forms will be individuals who express interest in serving in volunteer governance or committee roles within the OPTN. This includes a broad and diverse group of stakeholders involved in or connected to organ donation and transplantation, such as: transplant professionals (*e.g.*, physicians, surgeons, coordinators, administrators), organ procurement organization personnel, histocompatibility experts, researchers, patients, living donors, family members, caregivers, and members of the public with relevant expertise (*e.g.*, ethics, finance, governance, public policy, or operations). Respondents may be employed or unaffiliated individuals and will represent a wide range of professional disciplines, lived experiences, and geographic regions across the United States, helping to support a more dynamic and representative governance process. Respondents completing the COI forms and attestation forms will be individuals who have been elected or appointed to committee and BOD positions for the OPTN.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested in the applications, COI, and attestation forms. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below. HRSA calculated estimated burden hours based on internal testing for completing each form.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
OPTN BOD Application *	304	1	304	1.50	456.00
OPTN Committee Application *	838	1	838	1.25	1,047.50
OPTN BOD and Committee Annual COI Form	505	1	505	0.17	85.85
OPTN BOD Tri-Annual COI Form	74	3	222	0.08	17.76
OPTN BOD Ad hoc COI Form **	74	24	1,776	0.08	142.08
OPTN Attestation Form	505	1	505	0.08	40.40
OPTN Code of Conduct Form	505	1	505	0.08	40.40
OPTN Confidentiality Agreement	505	1	505	0.08	40.40
Total			5,160		1,870.39

* Estimated responses per year, every 2 to 3 years.

** Board members submit ad hoc conflict-of-interest forms prior to each monthly meeting, and before any ad hoc Board Meeting or Executive Board meeting with specific institution-based discussion.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy P. McNulty,

Deputy Director, Executive Secretariat.

[FR Doc. 2026-16054 Filed 8-5-26; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting website (<https://videocast.nih.gov/watch/c3123b11-02ce-11f1-9f14-124f0a52e769>). Registration is not required to access the videocast.

The meeting will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Dental and Craniofacial Research Council.

Date: September 9, 2026.

Open: 9:30 a.m. to 12:30 p.m.

Agenda: For the discussion of programs; opening remarks; report of the Director, NIDCR; and other business of the Council.

Address: National Institute of Dental Craniofacial Research, 31 Center Drive, Bethesda, MD 20892. Virtual Meeting.

Closed: 12:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institute of Dental Craniofacial Research, 31 Center Drive, Bethesda, MD 20892. Virtual Meeting

Contact Person: Latarsha J. Carithers, Ph.D., Acting Director, Division of Extramural Activities, National Institutes of Dental and Craniofacial Research, National Institutes of Health, 31 Center Drive, Room 2C39L, Bethesda, MD 20892, (301) 480-4151, latarsha.carithers@nih.gov.

Information is also available on the Institute's/Center's home page: <http://www.nidcr.nih.gov/about>, where an agenda and any additional information for the meeting will be posted when available.

Dated: August 4, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-16059 Filed 8-5-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review, Special Emphasis Panel; Career Development Grants.

Date: August 21, 2026.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kristin Goltry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 7198, Bethesda, MD 20892, (301) 435-0297, goltrykl@mail.nih.gov.